Written Testimony of the

Biotechnology Industry Organization

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The Biotechnology Industry Organization (BIO) represents more than 1,100 innovative biotechnology companies, along with academic institutions, state biotechnology centers, and related organizations in all 50 states. Entrepreneurs across the biotech industry are conducting groundbreaking research and are deeply invested in solving the problems that our nation and world face. Biotech companies are searching for new medicines to cure and treat devastating diseases, developing advanced biofuels and renewable chemicals to reduce our dependence on foreign oil, and improving agriculture to feed a growing world.

In the healthcare sector alone, there now are more than 200 biologic medicines and vaccines, including treatments for cancer, multiple sclerosis, diabetes, and numerous other diseases and rare conditions. In the last decade, innovative biotechnology companies and our partners in research universities have discovered over half of the scientifically novel treatments and therapies approved by the FDA. There are now more than 5,400 products in clinical development in biopharmaceutical labs across the U.S.

The biotechnology industry is also a powerful economic growth engine, directly employing 1.61 million Americans with an average salary of $82,697 and supporting an additional 3.4 million jobs. The vast majority of these employees work for small businesses – 90% of biotech companies employ fewer than 100 people. Biotech employees are scientific researchers, lab technicians, factory workers, and support staff in businesses across the country.

In order to protect these jobs and support biotech research and development, Congress should promote innovation in tax reform. A simpler tax code, lower corporate rate, and competitive territorial tax system will allow the United States to continue to lead the world in biotech research and development. The tax code should also support innovation through specific tax structures and incentives for pre-revenue, pre-tax R&D companies, given their continuing role in creating high-quality American jobs, stimulating long-term economic growth, and bolstering America's competitiveness on an increasingly global stage.

Importance of Tax Reform to Biotechnology

America currently leads the world in biotechnology, and BIO member companies are supporting high-quality jobs nationwide while also leading the search for groundbreaking medicines, renewable fuels, and other innovative technologies. As Congress considers reforms to the tax code, it is imperative that policymakers recognize the importance of the innovative R&D being conducted across the biotech spectrum, from start-ups and small businesses, to larger commercial-stage companies. Comprehensive tax reform that supports next generation

research and manufacturing will create jobs, spur investment, and encourage the growth of an R&D-intensive, modern American economy.

Multinational biotech innovators often face a competitive disadvantage due to the high U.S. corporate tax rate and America's burdensome worldwide tax system. BIO supports lowering the corporate rate and moving the United States to a territorial tax system in order to speed the delivery of innovative technologies to patients and consumers and stimulate job creation here in America.

Congress historically has recognized the importance of spurring innovation through the tax code. The R&D Tax Credit and Orphan Drug Tax Credit are two examples of the tax code providing incentives for innovative companies. However, constant uncertainty about whether the R&D credit will be extended makes tax planning extremely difficult. Though the credit was designed to support innovative research, companies cannot count on it and thus its purported benefits are undercut. Currently, 26 countries have more generous R&D incentives than the U.S. R&D credit. A permanent credit with an increased rate would do more to stimulate domestic innovation.

Congress enacted the Orphan Drug Tax Credit in 1983 to encourage biotechnology and pharmaceutical companies to develop therapies for rare diseases and conditions. By reducing the costs of developing drugs for smaller patient populations, the credit allows companies to develop products that would otherwise not be commercially feasible – helping millions of patients suffering from rare conditions get the new medicines they desperately need. In the 30 years since the initiation of this tax credit, the Food and Drug Administration (FDA) has approved more than 400 new drugs and biological products for rare diseases and has granted orphan designations to more than 2,000 compounds. In contrast, in the decade prior to 1983, fewer than 10 products were approved for rare diseases.

The Orphan Drug Tax Credit is a tremendously important incentive for manufacturers to engage in research and development of therapies for patients with rare diseases. Despite the success of the Orphan Drug Act, there is still huge unmet medical need. The National Organization for Rare Disorders (NORD) estimates that there are over 7,000 rare diseases, affecting up to 30 million Americans, for which there currently are no effective treatments.

BIO strongly supports both the R&D and Orphan Drug credits, as they are incredibly important elements of the current tax system and help to spur innovation in the life sciences. Comprehensive tax reform must be done in a way that preserves these incentives.

Promoting Investment in Small Business Innovation

The majority of companies in the biotech industry are pre-revenue small businesses without taxable income, and thus tax reform must go beyond the innovation-driving principles outlined above to address the unique issues faced by companies that are not yet taxpayers, but aspire to be. These research-intensive small biotechs are at the front end of a development timeline that, on average, will take more than a decade and cost more than $1 billion. Virtually all of this process will take place before a company has product revenue. These pre-revenue companies are unable to immediately utilize the incentives in the current tax code; instead, these credits are accumulated as deferred tax assets for later use to offset future profits and do not provide immediate or short-term tax benefits to companies or their investors. As Congress considers reforms to the tax code, it is vital that it address proposals to protect and promote small business innovation.

For growing biotech innovators, the tax code is extremely important due to their unique life cycle and development timeline. Their entire extended development period is undertaken in the context of tremendous risk and without the benefit of product revenue, so all operating capital must come from investors. These investor-backed companies depend on substantial private investment to provide the necessary funding for their capital-intensive research, development, and manufacturing. And yet, the current incentives for investors in the tax code are not sufficient by themselves to maximize biotech investment. The tax code should be reformed to support biotech research by providing incentives for private investors, such as other companies, individuals, and funds, to invest in innovative small businesses.

It is essential that investors in start-up businesses have a reason to invest early in a company's life cycle and continue that investment for a substantial period of time. A reformed tax code should include incentives for investors in high-risk industries, including pass-through structures to utilize certain tax assets and supportive capital gains treatment. Provisions that allow investors to utilize a small company's tax assets that cannot currently be used, or to expand their options for liquidity, would stimulate capital formation. By appropriately incentivizing innovation through the tax code, Congress has the opportunity to support and inspire breakthrough discoveries and bolster economic growth.

More should be done to support innovation by emerging companies, including allowing them to either immediately utilize their deferred tax assets to attract investment or maintain their value during transactions. The unique nature of innovative, pre-revenue companies with very long-term product cycles must be taken into account in tax reform, and the tax code should reflect the needs of these pre-revenue capital-intensive businesses.

Under the current tax system, companies are unable to use the tax code to attract investors, prevented from taking advantage of innovation and R&D incentives from a loss position, and hamstrung by a high corporate rate when they finally do become profitable. Congress should reform the tax code to make the corporate rate globally competitive, while also providing important incentives for the development and manufacturing of innovative products by companies of all sizes and revenue positions.

Proposals to Stimulate Next Generation R&D for Small, Pre-Revenue Biotechs

BIO supports a U.S. tax code that recognizes innovation as a crucial part of the 21st century American economy. Given the focus of this Subcommittee's hearing, the remainder of BIO's testimony will focus specifically on proposals aimed at small, pre-revenue companies.

Section 469 R&D Partnership Structures

In the 1980s, the growth of the biotech industry was fueled in part by the ability of growing companies to use R&D partnerships, in which individual investors would finance R&D projects and then utilize the operating losses and tax credits generated during the research process. These structures gave investors a tax incentive to support biotech research, which is heavily dependent on outside investors but often too risky or expensive to attract sufficient investment capital. However, the enactment of the passive activity loss (PAL) rules in 1986 prevented investors from using a company's losses to offset their other income, thus removing the incentive to support vital research in growing biotechs.

Prior to the 1986 changes, these structures had a proven track record in addressing the unique biotech funding challenge and in stimulating life-altering R&D. The research conducted through these partnerships contributed to the approval of several important new therapies – ranging from genetically-engineered proteins that were much safer and more reliable than the

conventionally harvested equivalents they replaced, to breakthrough drugs that have improved health outcomes and quality of life for large numbers of chronic disease patients.

BIO supports a limited exception from the PAL rules for R&D-focused pass-through entities in order to stimulate investment in groundbreaking research being conducted by emerging innovators. Under this proposal, small companies would be able to enter into a joint venture with an R&D project's investors. The losses and credits generated by the project would then flow through to the company and investors, who would be able to use the tax assets to offset other income. Instead of letting these deferred tax assets – which were designed to stimulate research in the first place – gather dust in an accountant's ledger book, this proposal allows them to be used immediately to move important research forward.

Reforming the PAL rules to allow investors to enjoy a more immediate return on their investment, despite the long and risky timeline usually associated with cutting-edge research, would incentivize them to invest at an earlier stage, when the capital is most needed. By limiting the exception to entities that devote a significant percentage of their expenses to R&D, have fewer than 250 employees, and have less than $150 million in gross assets, Congress can specifically support the growth of innovative small businesses.

In the 112th Congress, Representatives Jim Gerlach and Richard Neal introduced the High Technology Small Business Research Incentives Act (H.R. 6559), which would have granted this targeted PAL exemption to small, R&D-intensive pass-throughs. BIO strongly supported this legislation and urges the 113th Congress to consider it. Reforming Section 469 has the potential to stimulate capital formation for groundbreaking R&D and speed the development of cures and breakthrough medicines for patients suffering from serious and life-threatening diseases.

Section 382 Net Operating Loss (NOL) Reform

As discussed, biotechnology companies have a long, capital-intensive development period, meaning that they often undergo a decade of research and development without any product revenue prior to commercialization. During this time period, companies generate significant losses, which can be used to offset future gains if the company becomes profitable. However, Section 382 restricts the usage of NOLs by companies which have undergone an "ownership change." The law was enacted to prevent NOL trafficking, but small biotech companies are caught in its scope – their reliance on outside financing and deals triggers the ownership change restrictions, and thus their NOLs are rendered useless.

Under current law, most forms of biotech financing, including venture capital deals, partnerships, mergers, and IPOs, often qualify as an ownership change that triggers the Section 382 restriction. When NOLs are limited, the tax code negates the years of pre-revenue research that went into generating the losses, and subjects innovative companies to onerous taxation earlier than it should. Further, internal analysis of a company's ownership to determine whether NOLs will be limited by Section 382 can be costly and cause a further diversion of funds from important R&D.

BIO supports reform of Section 382 to exempt NOLs generated by qualifying research and development conducted by a small business from Section 382's restrictions. This change would allow growing companies the freedom to raise capital for innovative research without fear of losing their valuable NOLs. Additionally, the ability of a small business to maintain its NOLs makes it more attractive to investors and purchasers looking to take its research to the next level.

This targeted reform, restricted solely to losses generated by R&D, will support growing innovators as they engage in the search for the next generation of American technologies.

Section 1202 Capital Gains Reform

Private investment is key to small, research-intensive biotechs. Section 1202 allows investors to exclude from taxation a portion of their gain from the sale of a qualified small business (QSB) stock if they hold the stock for five years. Currently, the exclusion is set at 100%, but it will revert to 50% on January 1, 2014. BIO believes that the 100% exclusion should be made permanent in order to provide the maximum incentive for small company investors.

Section 1202 was designed to promote investment in growing businesses, but its overly restrictive size requirements prohibit innovative biotech companies from accessing valuable investment capital. Currently, QSBs must have gross assets below $50 million. The high costs of biotech research, coupled with valuable intellectual property (IP) and successive rounds of venture financing, often push growing biotechs over the $50 million gross assets limit and out of the QSB definition.

BIO supports a change to the QSB definition to include companies with gross assets up to $150 million, with that cap indexed to inflation. Increasing the gross assets limit will more accurately capture the true nature of innovative pre-revenue companies, while continuing to target Section 1202's investment incentives at small businesses. The current $50 million limit has hampered investment, and increasing it will stimulate important capital formation in emerging companies.

BIO also supports excluding IP from a small business's gross assets valuation. Innovative biotechs have valuable IP that is the basis of a company's research, but in and of itself the IP provides no cash to further said research. A growing company should not be punished for owning IP that might hold the key to a scientific breakthrough; rather, IP-centric companies are the very ones to whom Section 1202 should direct investment. Excluding the value of an innovator's IP from the gross assets test will incentivize investment in groundbreaking start-ups and small businesses.

Congress's original intent in enacting Section 1202 was to encourage and reward individuals for taking risks by investing in new ventures and small businesses. These proposed reforms will expand the outdated parameters of its current rules and lead to increased investment for innovative job creators. Providing incentives to invest in biotech research will increase the innovation capital available to research-intensive businesses and speed the development of groundbreaking medicines and other critical biotechnologies.

Conclusion

The current tax code is complicated and expensive to administer and comply with. Further, temporary tax rules are always in danger of expiring and result in extreme uncertainty for businesses trying to plan for their growth. Companies planning their development pipelines and investors considering biotech investments need to know what they can expect as these companies move through the development process. Ineffective innovation incentives combined with the world's highest tax rate among developed countries render the U.S. tax code unsuccessful in sufficiently stimulating next-generation research and development.

Congress has the opportunity to foster innovation, spur small business investment, and support the growth of an R&D-intensive, modern American economy. In order to create domestic jobs and ensure that the United States maintains its global leadership, tax reform

must lower the corporate rate and move towards a territorial system, while preserving innovation-driving incentives such as the R&D and Orphan Drug Tax Credits. But it must go further. Innovation by pre-revenue companies also must be promoted in tax reform if America is going to lead the way in the global economy.

The U.S. biotechnology industry remains committed to developing a healthier American economy, creating high-quality jobs in every state, and improving the lives of all Americans. Federal tax policy that recognizes the special demands placed on biotech companies and other highly innovative industries will speed the development of products to vastly improve the lives of Americans and people around the world. By recognizing the importance of innovation and the economic potential of the biotech industry, Congress can incentivize further development, create jobs, and improve America's economic health.

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